U.S. Food and Drug Administration

Department of Health and Human Services

FDA News

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Manufacturer of Over-the-Counter (OTC) Eye Drops Signs Consent Decree with FDA

The U.S. Food and Drug Administration (FDA) today announced that MBI Distributing, Inc. (MBI), also known as Molecular Biologics, an OTC drug manufacturer of eye drops and other products, has signed a consent decree that requires it to cease manufacturing and distributing drugs until it corrects manufacturing deficiencies and other violations at its Benicia, California facility. The consent decree was submitted to the U.S. District Court for the Eastern District of California by the Department of Justice on behalf of FDA and is subject to approval by the court.

MBI's product line includes eye drops sold under the brand names Oxydrops, Bright Eyes, Bright Eyes II, Clarity Vision for Life, Visitein, and Can-C, as well as several OTC pain relieving drugs. These products are sold by retailers nationwide.

This action is a result of FDA having determined that the firm has been manufacturing eye drops in a manner that does not conform to FDA's current good manufacturing practice requirements. The firm has not corrected violations noted during inspections, despite Agency efforts to have the company achieve compliance. Among other things, at FDA's most recent inspection, the firm lacked manufacturing controls to ensure that its eye drops were sterile.

FDA has also determined that two of the firm's eye drop brands, Visitein and Clarity Vision for Life, are unapproved drugs. In addition, three of the firm's OTC pain relieving drugs, Biogesic, Bio-Ice, and Bio-Heat, do not provide adequate warnings for their safe use.

Under the terms of the consent decree, MBI is enjoined from producing and distributing drugs until the firm corrects the manufacturing violations for its eye drops and its violations of the marketing approval and labeling requirements of the Federal Food, Drug, and Cosmetic Act.

The firm's poor manufacturing conditions have called into question the safety of its eye drops,and the lack of necessary warnings could undermine the ability of a consumer to safely use the firm's pain relieving drugs listed above. FDA therefore recommends that consumers, health care providers, and caregivers dispose of the Oxydrops, Bright Eyes, Bright Eyes II, Clarity Vision for Life, Visitein, and Can-C brands of eye drops and the Biogesic, Bio-Ice, and Bio-Heat pain relieving drugs and report any adverse events related to these products to MedWatch, the FDA's voluntary reporting program at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857-9787; or online at www.fda.gov/medwatch/report.htm.

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